4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0134]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Practices and Procedures; Formal Hearings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with general FDA administrative practices and procedures, including requests for formal hearings.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0134 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Practices and Procedures; Formal Hearings." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted

as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Administrative Practices and Procedures; Formal Hearings

OMB Control No. 0910-0191--Extension

This information collection supports FDA regulations found in part 10 (21 CFR part 10), parts 12 through 16 (21 CFR parts 12 through 16), and part 19 (21 CFR part 19). These regulations are established in accordance with the Administrative Procedures Act (5 U.S.C. subchapter 11) and implement administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in part 10 describe general administrative practices and include content and format instruction on submitting information to the Agency,

petitions for Agency action, and other topics such as the public calendar. Regulations in parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. The information collection also includes burden associated with waiver requests under § 10.19 (21 CFR 10.19). Unless a waiver, suspension, or modification submitted under § 10.19 is granted by the Commissioner of Food and Drugs, the regulations in part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because information associated with regulations in parts 12 through 16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we account only for burden we attribute to initiating the respective actions.

The information collection also includes burden associated with general meeting requests and correspondence submitted to FDA under § 10.65 (21 CFR 10.65), as well as general submissions associated with § 10.115 (21 CFR 10.115) which provides for public participation in the development of Agency guidance documents through requests to our Dockets Management Staff. Most burden attributable to recommendations found in FDA guidance documents is accounted for within information collection request (ICR) approvals respective to the topic-specific guidance document; however here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3).

The information collection also includes burden that may be associated with the procedural guidance document, "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" (September 2019), available for download from our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act. The guidance document provides information regarding our current thinking on interpreting section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)) and includes procedural instruction on submitting certain citizen petitions and petitions for stay of FDA action. The guidance document also describes how FDA interprets the provisions of

section 505(q) requiring that (1) a petition include a certification and (2) supplemental information or comments on a petition include a verification. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet made.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.19--request for waiver, suspension, or modification of requirements	7	1	7	1	7
10.30 and 10.31--citizen petitions and petitions related to ANDA[2], certain NDAs[3], or certain BLAs[4]	200	1	200	24	4,800
10.33--administrative reconsideration of action	9	1	9	10	90
10.35--administrative stay of action	12	1	12	10	120
10.65--meetings and correspondence	37	1	37	5	185
10.85--requests for Advisory opinions	1	1	1	16	16
10.115(f)(3)--submitting draft guidance proposals	26	1	26	4	104
12.22--Filing objections and requests for a hearing on a regulation or order	18	1	18	20	360
12.45--Notice of participation	5	1	5	3	15
Total					5,697

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Abbreviated New Drug Applications
[3] New Drug Applications
[4] Biologic License Applications

Based on submissions to FDA's Division of Dockets Management since our last evaluation of the information collection, we have made adjustments to burden estimates associated with the individual activities that correspond to the applicable provisions. As a result, the information collection reflects a decrease of 4,223 annual burden hours.

Dated: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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